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Arizona State Board of Pharmacy

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4425 W Olive Ave, Suite 140, Glendale, AZ 85302-3844
Web site: www.pharmacy.state.az.us
E-mail: info@azsbp.com

2005 Legislative Summary

The Pharmacy Omnibus Bill officially known as Senate Bill 1126 has been signed by Governor Janet Napolitano and will take effect sometime in August of this year. The Bill is the first major revision of the Arizona State Board of Pharmacy disciplinary processes in more than 15 years. It also adds two new members to the Board of Pharmacy, a pharmacy technician, and a practicing community pharmacist. The Board started licensing pharmacy technicians in May of 2004 and it was natural to add a pharmacy technician to the Board so that the technician member is able to represent this large and important segment of the pharmacy work force. A community pharmacist was added to keep the Board at an odd number of members and reduce the possibility for tie votes.

It is interesting that in the early 1970s it was necessary to reserve a member position on the Board for a hospital pharmacist because most members were community pharmacists, and now a majority of the pharmacist membership of the Board represents areas other than community pharmacy.

Some important new definitions are:

1. **Advisory Letter** – a non-disciplinary document sent to advise a licensee or permittee that continuation of his or her actions may lead to disciplinary action.
2. **Decree of Censure** – an official action taken by the Board that may include restitution of fees to a patient or consumer.
3. **Letter of Reprimand** – a disciplinary letter that is a public document, which informs a licensee or permittee that he or she is in violation of law and may be monitored by the Board.
4. **Professionally Incompetent** – incompetence that may endanger patients due to a lack of pharmaceutical knowledge or skills or failure to obtain a passing score on a pharmacy licensure examination.

The Bill also makes a very important addition to the Arizona Pharmacy Practice Act by making it a formal requirement for permittees and licensees to report to the Board any knowledge of licensure violations committed by another pharmacy licensee or permittee.

The Bill also modernized and modified the existing lists of disciplinary actions available to the Board by combining the various existing lists, which were dispersed throughout the previous version of the pharmacy act by consolidating them into two sections for licensees and one section for permittees. The areas for licensees are divided into two sections by placing all grounds for disciplinary actions against a pharmacist or pharmacist intern into the first section and against pharmacy technicians into the second section. The existing section, which listed grounds for disciplinary actions against a permittee, was also modified and more closely parallels the grounds for actions against licensees.

The Bill stipulates that prescription-only drugs may be dispensed and refilled upon receipt of an electronically transmitted prescription order or fax (subject to certain record-keeping requirements) and allows a pharmacist to change a written prescription order (strength, dosage form, quantity of drug, or directions for use) for a Schedule II drug if authorized verbally by the prescriber and documented on the original prescription.

The Bill makes the Arizona Pharmacy Act conform more closely to federal Drug Enforcement Administration regulations by specifying that prescription orders may be sent via fax for a Schedule II substance from the prescriber or prescriber's agent, for residents in hospice or long-term care facilities. The fax then serves as a written prescription. This was not mentioned previously, though it was allowed and some practitioners asked that it be spelled out more clearly.

A copy of the Bill is available on the Arizona Legislative Information Services Web site at the following link: www.azleg.state.az.us/DocumentsForBill.asp?Bill_Number=SB1126.

New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

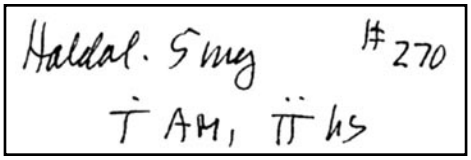
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

Disciplinary Actions – Board of Pharmacy (Actions Since April 2005 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

March 16, 2005

William Corona (Pharmacy Technician Trainee) – Revocation: Unauthorized presence of prescription drug in system as result of "for cause" biological drug screen.

Robert Balin and Aron Distributors (Non-Prescription Wholesale Permittee) – Revocation: conviction for improper sale(s) of precursor chemicals.

April 6, 2005

Marjorie Daily, RPh – Six-month to one-year suspension and five-year Pharmacists Assisting Pharmacists of Arizona substance abuse contract: "Controlled Substance violations."

David Garden, RPh – five-day suspension, three-year probation, $1,000 civil penalty: dispensing non-controlled substance prescription-only drugs without a valid prescription.

Mustafa Maher, RPh – Ten-day suspension, three-year probation, $5,000 civil penalty; Controlled Substance record-keeping violations.

Willo Pharmacy – One-year probation and $3,000 civil penalty: pharmacy open for business without a pharmacist present and unlicensed pharmacy technician working in pharmacy.

Disciplinary Actions – Other Health Care Practitioner Boards

Sakina F. Raza, MD (#23272) – no direct patient care or prescribing medications until approval from the Arizona Medical Board, effective April 18, 2005.

David A. Wilburt, MD (#9920) – no direct patient care or prescribing medications until approval from the Arizona Medical Board, effective April 14, 2005.

Kenley Moshe Remen, MD (#30159) – Summary Suspension effective March 23, 2005.

Wahid A. Ibrrahim, MD (#30413) – Summary Suspension effective March 23, 2005.

Joseph M. Scoggin, MD (#30290) – License inactivation with Cause effective March 29, 2005.

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The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Harlan "Hal" Wand, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Reneeta C. "Rene" Renganathan - Editorial Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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